IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' REPLY MEMORANDUM
TO PLAINTIFF'S OBJECTIONS TO EXHIBITS D-7391 AND D-7392

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Pfizer" or "Defendants") respectfully submit this Reply in response to Plaintiff's objections to trial exhibits labeled D-7391 and D-7392. (*See* Pl.'s Objections to Defs.' Ex. [223] at 1-2.)

The exhibit labeled D-7392 is an email from Dr. Donald Dobbs of the Food and Drug Administration ("FDA"), Center of Drug Evaluation and Research Division of Drug Information, to Dr. Alexander Ruggieri sent on April 1, 2008. This correspondence was in response to a February 8, 2008 message, a copy of which has been labeled D-7391, by Dr. Ruggieri to Dr. Steven Galson. While Plaintiff objects to the authenticity of D-7392, Dr. Ruggieri has sworn in an affidavit that this document constitutes "[a] true and correct copy of the FDA's April 1, 2008 email correspondence responding to [his] inquiry . . . ." (Ex. A, Dr. Ruggieri Affid. [MDL 1242] at ¶ 5.) This affidavit was filed with the MDL court on April 25, 2008, and a copy is attached herein as Exhibit A.

Rule 901(b)(1) provides that a proponent may authenticate a document by providing a witness with knowledge who attests that the document "is what it is claimed to be." As the recipient and addressee of the email, Dr. Ruggieri is undoubtedly a witness who has first-hand

knowledge and may attest that D-7392 accurately reflects the email he received.[1] As such, he has unambiguously testified that the April 1, 2008 email sent by Dr. Dobbs is a "true and correct copy" of what it purports to be. (Dr. Ruggieri Affid. [MDL 1242] at ¶ 5.) Any attempt by Plaintiff to impugn Dr. Ruggieri's veracity as to this matter would go merely to the weight and not the admissibility of the evidence.

Moreover, Plaintiff's hearsay objections are without merit. Even if this evidence were offered to prove the truth of the matter asserted, it would still be admissible under Federal Rule of Evidence 803(8). Rule 803(8) provides that the hearsay rule will not bar out-of-court statements from "[r]ecords, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth . . . the activities of the office or agency . . . ." This rule does not require, as a precondition to admissibility, that a proponent establish that the declarant had official speaking authority. Regardless, at the very least, Dr. Dobbs had apparent authority to speak on behalf of the FDA when he responded to a drug-related inquiry directed at the agency. Also, the fact that Dr. Dobbs sent the email from "DRUGINFO@fda.hhs.gov", rather than his personal work account, further supports the notion that he was speaking on behalf of the FDA and not merely expressing a personal opinion. As such, the April 1, 2008 email falls under the public record exception to the hearsay rule.

Furthermore, the statements in these documents would not be hearsay if not presented to prove the truth of the matter asserted, and Defendants may present them for such alternative purposes. For example, Dr. Dobbs wrote: "Patients taking these drugs have a high background rate of suicidal thoughts/behaviors, and it is not possible to tell from the AERS reports, whether

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[1] Plaintiff's irrelevant argument that the document does not satisfy Rule 901(b)(4) is beside the point because Defendants are not relying on that method to authenticate D-7392. Furthermore, Plaintiff's argument that Dr. Dobbs's personal work email account was listed on the email does nothing to undermine its authenticity. If anything, this may merely indicate that Dr. Dobbs sent the email from a general departmental account other than his personal work email. Finally, contrary to Plaintiff's contentions, there is no requirement to produce "routing information" for this email. It is sufficient that Dr. Ruggieri, a witness with first-hand knowledge, attests that the document accurately reflects the email he received.

the drug caused them." (D-7392.) Defendants may present this and other statements to show what the FDA considered when making labeling decisions as to Neurontin, and presentation of this evidence for that purpose does not constitute hearsay. The purpose would not be to show AERS reports *actually* are not indicative of suicide risk (i.e., the matter asserted), but rather to show what the FDA does and does not consider when making decisions about labeling.[2] Dr. Dobbs also explained: "*In the agency's view*, the only way to establish whether or not the drugs are responsible for suicidality is to analyze controlled data." (*Id.* (emphasis added).) This statement is also relevant to showing the FDA's internal decision-making process and thereby providing the jury with the appropriate regulatory context. This April 1, 2008 email essentially shows notice of the type of evidence required by FDA, which is consistent with testimony of other scientists in the field as to what type of evidence is actually probative of the causation issue in question. Because this constitutes a purpose other than establishing the truth of the matter asserted, the hearsay rule is not a barrier to admitting this correspondence between Dr. Ruggieri and the FDA.

CONCLUSION

For the reasons set forth above, the Court should disregard Plaintiff's groundless objections and admit D-7391 and D-7392 into evidence.

[2] Plaintiff's argument – regarding the degree of Dr. Dobbs's authority to speak on behalf of the FDA – goes to the weight and not the admissibility of the evidence. In any case, regardless of whether he was officially authorized to speak on behalf of the FDA, his statements may still provide some insight into how the FDA's internal decision-making process works.

Dated: May 14, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 14th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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